REMARKS

Claim 27 has been objected to because of certain informalities. As suggested by the Examiner, Claim 27 has been amended to depend from Claim 26. With this amendment and explanation, it is assumed that the objection to Claim 27 has been overcome.

Claims 25, 26, 28, 29, 63 and 64 have been rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al. (U.S. Patent Application Publication No. 2003/0050547). Claim 27 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. in view of Schulman et al. (U.S. Patent No. 5,497,772). Claims 56-58 and 60-61 have been similarly rejected as being unpatentable over Lebel et al. in view of Cheney, II et al. (U.S. Patent No. 5,391,250), Claim 59 as being unpatentable over Lebel et al. in view of Cheney, II et al. as applied to Claims 56-58 and 60-61 above and further in view of Schulman et al. (U.S. Patent Application Publication No. 2001/0051768), Claim 62 as being unpatentable over Lebel et al. in view of Cheney, II et al. as applied to Claims 56-58 and 60-61 above and further in view of Pantages et al. (U.S. Patent Application Publication No. 2001/0029337), Claim 65 as being unpatentable over Lebel et al. in view of Kirsch et al. (U.S. Patent No. 6,503,225), and Claims 68-69 as being unpatentable over Lebel et al. in view of Webber (U.S. Patent No. 6,166,614). Reconsideration of these claims is respectfully requested.

Lebel et al. disclose a sensing apparatus 10 that includes a sensor lead 12, a first end 14 comprising a connector 16 and a second end 18 comprising a sensor module 20. Molded onto each end of the sensor module 20 are beads 22. An ogive, or bullet shaped, tip 24 attaches to a bead 22 that is opposite the sensor lead 12 such that the entire assembly is streamlined in a fluidic environment, such as a bloodstream. The sensor lead 12 comprises tubing that attaches to the ogive tip 24. The entire sensing apparatus 10 may be placed in a vein or other area within a human body. Paragraph 30. The connector 16 may be a male, female or other type connector. The connector 16 may provide for multiple conductive paths, thereby accommodating a variety of sensor lead 12 configurations. Paragraph 31. A sensor module 20 may include a substrate 30 having a sensing element side 32 and an electronics side 34. The substrate 30 may be made from ceramic or other materials. As can be seen in FIG. 2A, electrodes 36 may be deposited onto the sensing element side 32 of the substrate 30. The electrodes 36 may interface with a sensing

element. The electronics side 34 of the substrate 30 may include a lid 38 that covers a variety of electronics, such as, for example, an integrated circuit 40 and a capacitor 42. The electronics side 34 of the substrate 30 may also include welding pads 44 to which wire leads may be welded as well as other types of pads and traces common to electronic circuitry. The electrodes 36 and the electronics on the electronics side 34 of the substrate 30 provide the basis for electrochemical measurement. According to one embodiment of the invention, the sensor module 20 may be utilized for oxygen sensing. However, the sensor module is not limited to this application and may also be utilized in other applications such as, for example, for ion, neurotransmitter or nitric oxide sensing. Paragraph 32. Wrapped around the core 60 in a helical fashion is a conductive element 62. The conductive element 62 may be a flat cable or ribbon cable having multiple conductor wires. Paragraph 42. According to an embodiment of the present invention the conductive element 62 may be a flat cable having four wires 68 as shown in FIG. 6B. The diameter of each wire 68 may be as thin as one one-thousandth of an inch or thinner and the entire cable may be molded with TEFLON or another insulator such that the wires are insulated from one another. Paragraph 45. A window may be cut in the outer tubing of the sensor lead 12 over the second spacing element 54. In glucose sensing applications, a typical window width may be five thousandths of an inch, or may be ten to twenty thousandths of an inch. In addition, window depth may be anywhere from about four thousandths of an inch to ten thousandths of an inch. Paragraph 52.

Cheney, II et al. disclose thin film electrochemical sensors of the type used, for example, in subcutaneous or transcutaneous monitoring of blood glucose levels in a diabetic patient. Col. 1, lines 10. One or more sensors 10 are formed on a rigid flat substrate 12, such as a glass plate. The sensors 10 are formed in a manner which is compatible with photolithographic mask and etch techniques, but wherein the sensors are not physically adhered or attached directly to the substrate 12. Col 3, lines 24-29. In a glucose monitoring application, the thin film sensor 10 is placed transcutaneously so that the distal end electrodes 24 are in direct contact with patient blood or extracellular fluid, and wherein the contact pads 26 are disposed externally for convenient connection to a monitoring device (not shown). Col. 3, lines 41-47.

Kirsch et al. disclose a device for removal of gas bubbles and dissolved gasses in liquid. The device 10 can be coupled to any fluid infusion line, such as the catheter flush line 12 as

shown in FIG. 1, for removal of gas bubbles and dissolved gas from the fluid passing through the line. The device 10 includes a fluid-tight housing 20, which is preferably fabricated from a rigid FDA grade material, such as polycarbonate, as a "T" or "Y" fitting. The housing 20 generally comprises a body portion 22, and first and second ends 24, 26. First end 24 comprises an inlet port 28 for receiving a liquid, and second end 26 comprises an outlet port 30 for discharging the degassed liquid for delivery to an internal delivery site of a patient. Col. 3, lines 34-45. At least one, and preferably a plurality of hollow fiber membranes 50 extend generally axially through the housing 20, from adjacent the first end 24 to adjacent the second end 26. Each fiber extends between a first end adjacent the inlet 28 and a second end adjacent the outlet 30. The fibers 50 can be a microporous hydrophobic hollow fiber membrane, such as are available commercially as polyolefin membranes. Example materials include: polypropylene, polyethylene, or polymethylpentene. Col. 4, lines 9-17. Although microporous hydrophobic hollow fiber membranes are described above, any porous hollow fiber material, whether hydrophobic or hydrophilic, can be used to form the fibers 50, with the application of a thin coating or skin of a polymer having suitable permeability to the dissolved gasses (for example, oxygen, nitrogen, carbon dioxide) in the aqueous fluid passed through the tubing 12, but rendering the pores of the fibers 50 impermeable to passage of the aqueous fluid therethrough. Example polymer coatings include silicones, polymethylpentene, and other FDA grade polymers. Col. 9, lines 35-45.

Amended Claim 25 is patentable by calling for a small-diameter probe for use with an introducer in a patient having a vessel carrying blood to ascertain characteristics of the blood comprising a cannula having proximal and distal extremities and a diameter ranging from 0.010 to 0.035 inch, the distal extremity of the cannula being adapted to be inserted into the vessel of the patient, an oxygen and carbon dioxide sensor assembly disposed in the distal extremity of the cannula for providing an electrical signal when the cannula is disposed in the blood.

None of the cited references disclose a small-diameter probe of the type called for in amended Claim 25 the includes a cannula having a diameter ranging from 0.010 to 0.035 inch. In this regard, for example, Lebel et al. is silent as to the diameter of sensing lead 12 therein. Further, it is clear from the components and dimension of the sensing apparatus 10 thereof that the lead 12 does not have a diameter ranging from 0.010 to 0.035 inch. Further, it is not clear from any of the cited references that a small diameter probe of the type called for in amended

Claim 25 would be possible to construct. There is no suggestion or disclosure from the cited references that the internal components of the probes therein can be scaled down to a size that permits a probe as called for in amended Claim 25.

The very small diameter of the probe of Claim 25 is an important feature of the invention as it facilitates entry and placement of the probe in a vessel of the patient, and minimizes trauma to the patient during such a procedure.

Claims 26-29 and 56-69 depend from Claim 25 and are patentable for the same reasons as Claim 25 and by reason of the additional limitations called for therein. For example, Claim 65 is patentable by, together with intervening Claims 63-64, providing that the entire cannula is made of polymethylpentene. Contrary to the assertion of the Examiner, Kirsch et al. does not disclose a probe of the type called for in Claim 65. In fact, Kirsch et al. does not disclose any type of probe that includes polymethylpentene. Instead, and as discussed above, Kirsch et al merely disclose a device for removal of gas bubbles and dissolved gas from the fluid passing through the line that has a fluid-tight housing 20 provided with a plurality of hollow fiber membranes 50 that can be a microporous hydrophobic hollow fiber membrane, such as are available commercially as polyolefin membranes with disclosed example materials that include polypropylene, polyethylene, or polymethylpentene.

New Claim 70 is different in scope than the claims of record and patentable for reasons similar to those discussed above with respect to Claim 65 by calling for a probe that includes a cannula having proximal and distal extremities, an oxygen and carbon dioxide sensor assembly disposed in the distal extremity of the cannula for providing an electrical signal when the cannula is disposed in the blood, the cannula being made of polymethylpentene in the vicinity of the oxygen and carbon dioxide sensor assembly.

New Claims 71-73 depend from Claim 70 and are patentable for the same reasons as Claim 70 and by reason of the additional limitations called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that

the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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